

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

AT CLARKSBURG

NOVARTIS PHARMACEUTICALS
CORPORATION, NOVARTIS
CORPORATION, NOVARTIS AG, and
NOVARTIS PHARMA AG

Plaintiffs,

V.

MYLAN, INC. and MYLAN
PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 1:14-CV-111-IMK

PLAINTIFFS' ANSWER TO MYLAN'S COUNTERCLAIMS

Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG (collectively, “Novartis”) respond to the Counterclaims of Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, “Mylan”) as follows:

COUNTERCLAIMS

Nature of the Counterclaims

1. Paragraph 1 contains conclusions of law for which no response is required.

Parties

2. Upon information and belief, admitted.
3. Upon information and belief, admitted.
4. Admitted.
5. Admitted.
6. Admitted.

7. Admitted.

Jurisdiction and Venue

8. Paragraph 8 contains conclusions of law for which no response is required.

9. Paragraph 9 contains conclusions of law for which no response is required. To the extent a response is required, Novartis states that the parties' dispute should be litigated in the District of Delaware, where Novartis filed suit first.

10. Paragraph 10 contains conclusions of law for which no response is required.

Factual Background

11. Admitted.

12. Admitted.

13. Admitted.

14. Admitted.

15. Upon information and belief, admitted.

16. Novartis admits that Mylan sent Novartis a letter ("the Notice Letter") dated May 13, 2014, notifying Novartis that it had submitted Abbreviated New Drug Application ("ANDA") No. 206585 to the U.S. Food and Drug Administration. Novartis also admits that the Notice Letter stated that ANDA No. 206585 contained a "Paragraph IV certification" asserting that certain claims of U.S. Patent Nos. 6,465,504 ("the '504 Patent") and 6,596,750 ("the '750 Patent") are invalid, unenforceable, and/or will not be infringed by the product that is the subject of ANDA No. 206585. Novartis further admits that Mylan's Notice Letter provided Novartis with an Offer of Confidential Access. Novartis denies any and all remaining allegations in Paragraph 16.

COUNT 1

(Declaratory Judgment of Non-Infringement of the '504 Patent)

17. Novartis hereby incorporates the responses set forth in Paragraphs 1 through 16.

18. Paragraph 18 contains conclusions of law for which no response is required.

19. Paragraph 19 contains conclusions of law for which no response is required.

20. Paragraph 20 contains conclusions of law for which no response is required.

21. Admitted.

22. Admitted that Novartis maintains that Mylan is liable for infringement of the '504 Patent. Novartis denies any and all remaining allegations in Paragraph 22.

23. Denied.

24. Denied.

25. Denied.

26. Denied.

27. Denied.

COUNT 2

(Declaratory Judgment of Non-Infringement of the '750 Patent)

28. Novartis hereby incorporates the responses set forth in Paragraphs 1 through 27.

29. Paragraph 29 contains conclusions of law for which no response is required.

30. Paragraph 30 contains conclusions of law for which no response is required.

31. Paragraph 31 contains conclusions of law for which no response is required.

32. Admitted.

33. Admitted that Novartis maintains that Mylan is liable for infringement of the '750 Patent. Novartis denies any and all remaining allegations in Paragraph 33.

34. Denied.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

COUNT 3

(Declaratory Judgment of Invalidity of the '504 Patent)

39. Novartis hereby incorporates the responses set forth in Paragraphs 1 through 38.

40. Paragraph 40 contains conclusions of law for which no response is required.

41. Paragraph 41 contains conclusions of law for which no response is required.

42. Paragraph 42 contains conclusions of law for which no response is required.

43. Admitted.

44. Admitted that the '504 Patent is valid and enforceable. Novartis denies any and all remaining allegations in Paragraph 44.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

COUNT 4

(Declaratory Judgment of Invalidity of the '750 Patent)

51. Novartis hereby incorporates the responses set forth in Paragraphs 1 through 50.

52. Paragraph 52 contains conclusions of law for which no response is required.

53. Paragraph 53 contains conclusions of law for which no response is required.

54. Paragraph 54 contains conclusions of law for which no response is required.

55. Admitted.

56. Admitted that the '750 Patent is valid and enforceable. Novartis denies any and all remaining allegations in Paragraph 56.

57. Denied.

58. Denied

59. Denied.

60. Denied.

61. Denied.

62. Denied.

PRAYER FOR RELIEF

WHEREFORE, Novartis respectfully requests that the Court enter judgment:

- a) Dismissing Mylan's Counterclaims with prejudice;
- b) Awarding Novartis the relief that it requested in its Complaint; and
- c) Awarding Novartis such other relief as the Court deems just and proper.

/s/James F. Companion

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CERTIFICATE OF SERVICE

I hereby certify that on December 23, 2014, the foregoing **PLAINTIFFS' ANSWER TO MYLAN'S COUNTERCLAIMS** was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification to the following registered attorneys that the document has been filed and is available for viewing and downloading:

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